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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,820	05/06/2002	Wolf-Georg Forssmann	P67431US0	8031

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EXAMINER	
MAYER, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,820	FORSSMANN ET AL.	
	Examiner	Art Unit	
	Suzanne M. Mayer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-28* is/are pending in the application.

4a) Of the above claim(s) *16,17 and 21-28* is/are withdrawn from consideration.

5)☒ Claim(s) *15* is/are allowed.

6)☒ Claim(s) *20* is/are rejected.

7)☒ Claim(s) *18 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 16-17 and 21-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 26 April, 2004.

2. Applicant's election with traverse of Group 1 in the reply filed on 26 April, 2004 is acknowledged. The traversal is on the ground(s) that the serine proteinase inhibitor is novel over the prior art. This is not found persuasive because a protein identical to the sequence disclosed in SEQ ID No:2 has been identified in PCT US98-27059. However, upon further consideration, restriction of the claims has been re-assessed and re-restricted to the following 11 groups. The elected Group I will still be examined and is final, however, claims 18 and 19 have been added to this group and will therefore also be included in the examination.

The requirement is still deemed proper and is therefore made FINAL.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 15 and 18-20 drawn to a serine protease inhibitor having the amino acid sequence according to SEQ ID No:1, and a medicament used to treat various diseases.

Group 2, claim 16, drawn to a fragment of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino acid or a peptide with up to 100 amino acids, and X is SEQ ID No:2.

Group 3, claim 16, drawn to a fragment of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino acid or a peptide with up to 100 amino acids, and X is SEQ ID No:3.

Group 4, claim 16, drawn to fragments of a serine protease inhibitor having the amino acid sequence R1-X-R2, wherein R1 is NH2, an amino acid or a peptide with up to 100 amino acids, and R2 is COOH, CONH2, an amino acid or a peptide with up to 100 amino acids, and X is SEQ ID Nos: 4-6.

Since SEQ ID NOs: 4-6 overlap in scope according to the generic formula R1-X-R2, for example if R1=NH2, X=SEQ ID No:4 and R2=100, the next 100 amino acids according to SEQ ID No:1 after SEQ ID No: 4 would encompass SEQ ID No:5. Therefor, an election of species is required for Group 4 where X= one of SEQ ID No: 4, 5 or 6.

Group 5, claims 17-19 and 28, drawn to a nucleic acid (SEQ ID NO: 7) coding for a serine protease inhibitor according to claim 15, and a medicament used for treating various diseases. Please note that SEQ ID Nos: 8-12 do not code for a serine protease inhibitor having the amino acid sequence according to SEQ ID No:1.

Group 6, claim 21, drawn to the use of a serine protease inhibitor according to SEQ ID No:1 as a medicament.

Group 7, claim 21, drawn to the use of a nucleic acid encoding a serine protease inhibitor, according to claim 15, as a medicament.

Group 8, claim 22, drawn to use of a nucleic acid encoding a serine protease inhibitor used in preparing medicament.

Group 9, claims 23, 25 and 26, drawn to antibodies or antibody fragments against epitopes of a serine protease inhibitor having the amino acid sequence according to SEQ ID No:1, and a diagnostic agent containing the same.

Group 10, claim 24, drawn to poly- or oligonucleotides which will hybridize to regions of the cDNA or corresponding RNA under stringent conditions and optionally prevent the expression of coding regions of the genes coding for a serine protease inhibitor having the same amino acid sequence according to SEQ ID No:1.

Group 11, claim 27, drawn to method of preparing a medicament using either antibodies or antibody fragments according to claim 23.

3. The inventions listed as Groups 1-11 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature which links Groups 1-11 is that they all relate to a serine protease inhibitor encoded by SEQ ID No:1 or fragments thereof such as the fragment of SEQ ID No:2. However, an encoded human secreted protein having a serine protease inhibitor type sequence, SEQ ID No: 127 which is a 554 amino acid sequence that has been disclosed in PCT US98-27059. This amino acid sequence possesses the amino acid sequence according to SEQ ID No:2 and represents amino acids numbers 162-196 of SEQ ID No:127 from the PCT US98-27059 application.

Therefore, the technical feature linking the inventions of Groups 1-11 does not constitute a special technical feature as defined by PCT Rule 13.2, as it is not an advance over the prior art. Since, according to PCT Rule 13.2, the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which fulfills this role, the current claimed subject matter lacks unity of invention according to PCT Rule 13.1.

Specification

4. Content of the specification is objected to. The correct format of the specification is outlined below. In particular, the present Application lacks (e)-(f). Appropriate correction is required.

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(k) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Objections

5. Claims 18 and 19 are objected to because they contain non-elected subject matter (e.g. DNA).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is directed to the treatment for "the prophylaxis of lung emphysema formation in deficiencies of α_1-proteinase inhibitor". This claim reads upon the

prevention of lung emphysema in α_1-proteinase inhibitors, which is impossible. It would be clearer to replace 'in' with 'because of deficiencies of α_1-proteinase inhibitor'.

Claim 20 is also rejected as it provides for the use of the serine protease inhibitor from claim 15 for the preparation of a medicament used for treatment of various diseases. However, since the claim does not set forth any steps involved in the treatment process, it is unclear what sort of treatment applicant is intending to carry out. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 20 is also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

8. Claim 20 is rejected. Claims 18 and 19 are objected to. Claim 15 is allowed. Claims 18 and 19 would be allowable if rewritten to remove the non-elected subject matter.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached Monday to Fridays from 8.30am-5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
14 June, 2004

ROBERT A. WAX
PRIMARY EXAMINER